

In the Claims

Claim 1 (Currently amended): A method for modulating an immune response comprising administering ~~a nucleic acid sequence encoding IL-12, IFN- γ , or both IL-12 and IFN- γ , or biologically active fragments of any of the foregoing; and an operably linked promoter sequence; to a patient in need thereof.~~ an effective amount of a nucleic acid sequence encoding IL-12, and an operably linked promoter sequence; and an effective amount of a nucleic acid sequence encoding IFN- γ , and an operably linked promoter sequence; to a patient in need thereof, resulting in an increase of Th1-type cytokine production and a decrease of Th2-type cytokine production within the patient.

Claim 2 (Currently amended): The method of claim 1, wherein the ~~nucleic acid sequence encodes human IL-12, human IFN- γ , or both human IL-12 and human IFN- γ~~ IL-12 is human IL-12, and wherein the IFN- γ is human IFN- γ .

Claim 3 (Currently amended): The method of claim 1, wherein ~~the IL-12 comprises the p35 subunit, the p40 subunit, or both the p35 subunit and the p40 subunit~~ the IL-12 comprises the p35 subunit and the p40 subunit, wherein the p35 subunit comprises the amino acid sequence of SEQ ID NO:8, and wherein the p40 subunit comprises the amino acid sequence of SEQ ID NO:10.

Claim 4 (Currently amended): The method of claim 1, wherein ~~the IL-12 comprises the p35 subunit, the p40 subunit, or both the p35 subunit and the p40 subunit~~ a p35 subunit and a p40 subunit, wherein the p35 subunit is operably linked to a promoter sequence, and wherein the p40 subunit is operably linked to a promoter sequence.

Claim 5 (Cancelled)

Claim 6 (Currently amended): The method of claim 1, wherein the IFN- γ comprises the amino acid sequence of SEQ ID NO:12, ~~or a biologically active fragment or homolog thereof.~~

Claim 7 (Currently amended): The method of claim 1, wherein the nucleic acid sequence ~~encoding IL-12, or both IL-12 and IFN- γ , comprises SEQ ID NO:7 or SEQ ID NO:9, or a biologically active fragment or homolog of any of the foregoing encoding IL-12 comprises SEQ ID NO:7 and SEQ ID NO:9.~~

Claim 8 (Currently amended): The method of claim 1, wherein the nucleic acid sequence ~~encoding IFN- γ , or both IL-12 and IFN- γ , comprises SEQ ID NO:11, or a biologically active fragment or homolog thereof~~ encoding IFN- γ comprises SEQ ID NO:11.

Claim 9 (Currently amended): The method of claim 1, wherein the ~~nucleic acid sequence is~~ nucleic acid sequences are administered with a pharmaceutically acceptable carrier.

Claim 10 (Cancelled)

Claim 11 (Currently amended): The method of ~~claim 10~~ claim 1, wherein the ~~expression vector is a DNA plasmid~~ nucleic acid sequences are administered within separate DNA plasmids.

Claim 12 (Currently amended): The method of ~~claim 10~~ claim 1, wherein the ~~expression vector is a viral vector~~ nucleic acid sequences and promoter sequences are administered within a viral vector.

Claim 13 (Cancelled)

Claim 14 (Original): The method of claim 1, further comprising administering an antigen to the patient.

Claim 15 (Original): The method of claim 14, wherein the antigen is selected from the group consisting of a protein, peptide, glycoprotein, carbohydrate, lipid, glycolipid, hapten conjugate, recombinant nucleotides, killed or attenuated organism, toxin, toxoid, and organic molecule.

Claims 16-17 (Cancelled)

Claim 18 (Currently amended): The method of claim 14, wherein the antigen is administered to the patient with the ~~nucleic acid sequence~~ nucleic acid sequences and a pharmaceutically acceptable carrier.

Claim 19 (Original): The method of claim 1, wherein the patient is human.

Claim 20 (Currently amended): A pharmaceutical composition comprising a nucleic acid sequence encoding ~~IL-12, IFN- γ , or both IL-12 and IFN- γ , or a biologically active fragment of any of the foregoing; an operably linked promoter sequence~~ IL-12 and an operably linked promoter sequence; a nucleic acid sequence encoding IFN- γ and an operably linked promoter sequence; and a pharmaceutically acceptable carrier.

Claim 21 (Currently amended): The pharmaceutical composition of claim 20, wherein said ~~nucleic acid sequence encodes human IL-12, human IFN- γ , or both human IL-12 and human IFN- γ~~ IL-12 is human IL-12, and wherein said IFN- γ is human IFN- γ .

Claim 22 (Cancelled)

Claim 23 (Currently amended): The pharmaceutical composition of ~~claim 22~~ claim 20, wherein said ~~p35 subunit comprises the amino acid sequence of SEQ ID NO:8, or a biologically active fragment or homolog thereof, and wherein said p40 subunit comprises the amino acid sequence of SEQ ID NO:10, or a biologically active fragment or homolog thereof~~ wherein said IL-12 comprises a p35 subunit and a p40 subunit, wherein the said p35 subunit comprises the amino acid

sequence of SEQ ID NO:8, and wherein said p40 subunit comprises the amino acid sequence of SEQ ID NO:10.

Claim 24 (Currently amended): The pharmaceutical composition of claim 20, wherein said IFN- γ comprises the amino acid sequence of SEQ ID NO:12, ~~or a biologically active fragment or homolog thereof.~~

Claim 25 (Currently amended): The pharmaceutical composition of claim 20, wherein said nucleic acid sequence encoding IL-12, ~~or both IL-12 and IFN- γ , comprises SEQ ID NO:7 or SEQ ID NO:9, or a biologically active fragment or homolog of any of the foregoing~~ comprises SEQ ID NO:7 and SEQ ID NO:9.

Claim 26 (Currently amended): The pharmaceutical composition of claim 20, wherein said nucleic acid sequence encoding IFN- γ , ~~or both IL-12 and IFN- γ , comprises SEQ ID NO:11, or a biologically active fragment or homolog thereof~~ comprises SEQ ID NO:11.

Claim 27 (Currently amended): The pharmaceutical composition of claim 20, wherein said composition comprises an expression vector containing said ~~nucleic acid sequence and said operably linked promoter sequence~~ nucleic acid sequences and said promoter sequences.

Claim 28 (Currently amended): The pharmaceutical composition of ~~claim 27~~ claim 20, ~~wherein said expression vector is a DNA plasmid, wherein said nucleic acid sequences are contained within separate DNA plasmids.~~

Claim 29 (Currently amended): The pharmaceutical composition of ~~claim 27~~ claim 20, ~~wherein said expression vector is a viral vector~~ wherein said nucleic acid sequences and said promoter sequences are contained within a viral vector.

Claim 30 (Original): The pharmaceutical composition of claim 20, wherein said composition further comprises an antigen.

Claim 31 (Original): The pharmaceutical composition of claim 30, wherein said antigen is selected from the group consisting of a protein, peptide, glycoprotein, carbohydrate, lipid, glycolipid, hapten conjugate, recombinant nucleotides, killed or attenuated organism, toxin, toxoid, and organic molecule.

Claims 32-42 (Cancelled)

Claim 43 (New): A method for modulating an immune response comprising administering an effective amount of a plasmid comprising a nucleic acid sequence encoding IL-12, and an operably linked promoter sequence; and an effective amount of a plasmid comprising a nucleic acid sequence encoding IFN- γ , and an operably linked promoter sequence, resulting in an increase of Th1-type cytokine production and a decrease of Th2-type cytokine production within the patient.

Claim 44 (New): The method of claim 43, further comprising administering an antigen to the patient.

Claim 45 (New): The method of claim 44, wherein the antigen is an allergen.

Claim 46 (New): The method of claim 44, wherein the antigen comprises Kentucky blue grass (KBG) allergen extract.

Claim 47 (New): The method of claim 43, wherein the operably linked promoters are cytomegalovirus (CMV) promoters.

Claim 48 (New): The method of claim 44, wherein the antigen comprises Kentucky blue grass (KBG) allergen extract, and wherein the operably linked promoters are cytomegalovirus (CMV) promoters.

Claim 49 (New): The method of claim 43, wherein the patient is human.

Claim 50 (New): The method of claim 43, wherein the IL-12 comprises the amino acid sequences of SEQ ID NO: 8 and SEQ ID NO:10, and wherein the IFN- γ comprises the amino acid sequence of SEQ ID NO:12.

Claim 51 (New): The method of claim 43, wherein said administering further results in reduced serum IgE levels and increased IgG2a levels within the patient.

Claim 52 (New): The method of claim 43, wherein the patient suffers from a condition selected from the group consisting of allergy, allergic rhinitis, atopic dermatitis, asthma, allergic sinusitis, pulmonary fibrosis, and cancer.

Claim 53 (New): The method of claim 43, further comprising administering an antigen to the patient, wherein the plasmids are administered by a route selected from the group consisting of intramuscularly, orally, and intranasally.

Claim 54 (New): A pharmaceutical composition comprising a plasmid comprising a nucleic acid sequence encoding IL-12, and an operably linked promoter; a plasmid comprising a nucleic acid sequence encoding IFN- γ and an operably linked promoter; and a pharmaceutically acceptable carrier.

Claim 55 (New): The pharmaceutical composition of claim 54, wherein said composition further comprises an antigen.

Claim 56 (New): The pharmaceutical composition of claim 55, wherein said antigen is an allergen.

Claim 57 (New): The pharmaceutical composition of claim 54, wherein said IL-12 comprises the amino acid sequences of SEQ ID NO: 8 and SEQ ID NO:10, and wherein said IFN- γ comprises the amino acid sequence of SEQ ID NO:12.